MAIL STOP APPEAL BRIEF-PATENTS
Attorney Docket No.: 27233U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JONGEJAN et al.		Conf No.:	8025
Serial No.:	10/572,316	Art Unit:	3771
Filed:	March 17, 2006	Examiner:	BLIZZARD, C.J.

Title: **COMPLIANCE MONITOR AND METHOD**

APPEAL BRIEF

This is an appeal to the Board of Patent Appeals and Interferences from the decision of Examiner Christopher Blizzard, mailed April 23, 2010, rejecting claims 1-9, 11-22 and 25. Appellants filed a Notice of Appeal on June 30, 2010, making this Appeal Brief due by August 30, 2010. Accordingly, this paper is timely filed.

1. Table of Contents

2. The Real Party in Interest

The real party in interest in this appeal is NYCOMED GmbH.

3. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

4. Status of Claims

The status of the claims is as follows upon filing of this Appeal Brief:

Claims cancelled: 10, 23 and 24

Claims withdrawn from consideration but not cancelled: None

Claims pending: 1-9, 11-22 and 25

Claims objected to: None

Claims allowed: None

Claims rejected: 1-9, 11-22 and 25

The claims on appeal are 1-9, 11-22 and 25.

5. Status of Amendments

Appellants filed a Preliminary Amendment on March 17, 2006, in which claims 23-24 were canceled.

Appellants filed an Amendment and Response on June 22, 2009, in which claim 10 was canceled, and claims 1, 11, 12 and 19 were amended. The Examiner subsequently issued a final Official Action dated September 29, 2009, in which the amendments were entered but the rejection of all claims was maintained. Appellants filed an Amendment and Response, along with a Request for Continued Examination, on January 29, 2010, in which claim 1 was amended. The Examiner then issued a final Official Action dated April 23, 2010, as the first action after the Request for Continued Examination, in which the amendments were entered but all pending claims were rejected. As such, Appellants submit that claims 1-9, 11-22 and 25 are the currently pending claims of record. The claims listed in the claims appendix herein incorporate the claim amendments of the aforementioned Amendment and Response.

6. Summary of Claimed Subject Matter

Pending independent claim 1 recites a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth. Basis for this claim is found, for example, on page 1, lines 17-31, page 3, lines 1-10; page 5, lines 22-28; and page 7, lines 4-24.

7. Grounds of Rejection to be Reviewed on Appeal

A. Rejection of claims 1-5, 7, 8, 12-22 and 25 under 35 U.S.C. § 103(a)

Whether the identified claims are unpatentable under 35 U.S.C. § 103(a) as obvious over US Patent No. 5,809,997 to Wolf in view of US Patent No. 6,733,464 to Olbrich.

B. Rejection of claims 6 and 9 under 35 U.S.C. § 103(a)

Whether the identified claims are unpatentable under 35 U.S.C. § 103(a) as obvious over US Patent No. 5,809,997 to Wolf in view of US Patent No. 6,733,464 to Olbrich, as applied to claim 1 above, and further in view of US Patent No. 7,073,499 to Reinhold.

C. Rejection of claim 11 under 35 U.S.C. § 103(a)

Whether the identified claim is unpatentable under 35 U.S.C. § 103(a) as obvious over US Patent No. 5,809,997 to Wolf in view of US Patent No. 6,733,464 to Olbrich, as applied to claim 1 above, and further in view of US Patent No. 6,684,880 to Trueba.

8. Argument

A. Rejection of claims 1-5, 7, 8, 12-22 and 25 under 35 U.S.C. § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 U.S.C. § 103(a) as obvious over Wolf in view of Olbrich is improper and should be reversed.

Appellants respectfully submit that Wolf and Olbrich do not render Appellants' pending claims obvious for at least the following reasons.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under 35 USC § 103 by: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of non-obviousness.

Furthermore, to establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention

does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Also, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

With regard to motivation to combine references, **MPEP 2143** discusses the requirements of a *prima facie* case of obviousness. First, there must be some suggestion or motivation to combine the reference teachings or to modify the reference, and second, there must be a reasonable expectation of success. Finally, the prior art reference or references, when properly combined, must teach or suggest all the claim limitations.

Regarding motivation to properly combine or modify references, a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there can be no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference. See **MPEP 2143.01.**

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Wolf nor Olbrich (1) teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*, (2) indicate that the improvement suggested by the Examiner is a

predictable use of prior art elements according to their established functions, as required by *KSR*, or (3) provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

(1) The references do not teach or suggest every element of the claims

Claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

a. Neither Wolf nor Olbrich teach or suggest the claim limitation "a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose"

The Examiner alleges that Wolf describes "a sensor (1560) for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose (column 19, lines 21-41.)" Wolf at col. 19, lines 21-41, recites:

> FIG. 17c also shows the air flow path starting from the air holes inlet 1440, through the air channel 1561 and through the main-PCB 1540 at the edge where the air flow sensor fast response thermistor 1560 is mounted. The air flow continues through the access hole 1260 in the wall of the actuator 1575 that the dynamic sensing arm 1555 is also extended through. It is important to understand that when the user is inhaling the medication by breathing in, ambient air would enter normally into the actuator 1575

> around the sides of the vial/canister 1590, as is intended by the pharmaceutical manufacturer. Only a small fraction of ambient air enters through the accessory chronolog apparatus 1200, which allows the sensing of air flow. This channel of a fraction of the ambient air which enters the actuator 1575, has no interfering or altering effect of the medication being delivered out the mouthpiece 1585 of the commercially available vial/actuator combination 1220. The "states" of the air flow, as sensed by the fast response thermistor 1560 and the various tensions of force as they are applied to the strain gauge sensing area 1620 of the dynamic sensing arm 1555, shall be further discussed latter.

In contrast to the presently pending subject matter, Wolf's thermistor measures changes in air temperature to detect and validate the proper inhalation sequence. The thermistor of Wolf ***detects the temperature change of the airflow*** within the device as it is in use. The thermistor of Wolf does **not** detect the position of the device within the user's mouth, as required by the presently claimed subject matter.

Therefore, Wolf does not describe using "a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose" as recited in the claims. Accordingly, Appellants submit that Wolf fails to teach or suggest all the elements of the presently pending subject matter

Olbrich does not remedy the deficiencies of Wolf. Olbrich describes the use of a temperature sensor for recording body temperature for diagnostic evaluation or recording ambient temperature. *See* Olbrich at col. 8, line 55, to col. 9, line 17. **Olbrich does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**.

Appellants submit that the combination of references does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose. Importantly, Wolf describes the use of a fast

response thermistor to measure air temperature and validate the proper inhalation sequence. Wolf does not teach or suggest using the fast response thermistor to detect whether the device is "properly positioned."

b. Neither Wolf nor Olbrich teach or suggest the claim limitation "wherein the sensor is a temperature sensor for sensing body temperature"

The Examiner alleges that Wolf describes sensing airflow temperature, including airflow exhaled from the user. The examiner alleges that because the airflow that is sensed is from within the body, the temperature sensed is a "body temperature."

Body temperature is defined as "a measure of the body's ability to generate and get rid of heat." *See* WebMD article entitled "Body Temperature" attached herewith in the Evidence Appendix. The WebMD article also notes the various ways that body temperature can be measured. The article lists the mouth, ear, armpit, forehead and rectum as locations on the body where body temperature is measured. Further, the WebMD article noted that "[t]o get an accurate temperature, a person must be able to breathe through the nose." *See* also Vorvick et al., entitled "Temperature Measurement," attached herewith in the Evidence Appendix. One of ordinary skill in the art would understand that breathing through the mouth may affect the accuracy of the body temperature measurement when taken in the mouth.

In contrast to the presently pending subject matter, Wolf's fast response thermistor measures rapid changes in ***air*** temperature by measuring the temperature change to determine direction of airflow. *See* Wolf at col. 5, line 60, to col. 6, line 9. Accordingly, Wolf ***is not measuring body temperature*** as required by the presently claimed subject matter. In particular, Wolf is measuring air temperature change only to

determine direction of rapid changes in airflow and thereby to detect and validate the proper inhalation sequence. Wolf describes the proper inhalation sequence as consisting of the user inhaling cool temperature air flowing in one direction, followed by exhaled air of warmer temperature flowing in the opposite direction from inhalation. Therefore, a temperature change is caused by expanding inhalant possibly mixed with ambient air.

Further, as evidenced by the WebMD article, body temperature is measured at various locations of the body, including the mouth. When measuring body temperature via the mouth, the patient must keep their mouth closed and breathe through their nose to ensure accuracy of the body temperature measurement. Breathing through one's mouth during a temperature reading may affect the accuracy of the measurement. Clearly, measuring the temperature of one's breath, including one's breath during exhaling, is not measuring ***body*** temperature, but rather, ***air*** temperature. Therefore, Wolf teaches measuring ***air*** temperature to detect the sequence of inhaled air followed by exhaled air, and not ***body*** temperature as required by the presently pending claims.

Further, the device of Wolf is used to detect specific wave form characteristics or air flow. Wolf reads "This is possible by the distinct signature developed by the user drawing ambient air through inlet 316 and inhalant expanding within area 520 before being expelled." *See* Wolf at col. 15, line 66 through col. 16, line 2. Therefore, the device of Wolf does not measure the body temperature of the user but rather the wave form characteristics of the inhalant, i.e., the temperature change of the inhalant passing through the system rather than the absolute temperature. *See* Wolf at col. 12, lines 26-47. Wolf continues by stating in the same section that other suitable sensors include

audio sensors (to detect wave forms produced by audio elements) or piezo sensors (to detect changes in pressure as the inhalant passes through the appropriate path). As such, Wolf is clearly focused on detecting the temperature associated with the passage of the inhalant through the device rather than detecting the user's body temperature.

Therefore, Wolf does not describe using "a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose" and wherein "the sensor is a temperature sensor for sensing body temperature" as recited in the claims. Accordingly, Appellants submit that Wolf fails to teach or suggest all the elements of the presently pending subject matter

Olbrich does not remedy the deficiencies of Wolf. Olbrich describes the use of a temperature sensor for recording body temperature for diagnostic evaluation or recording ambient temperature. *See* Olbrich at col. 8, line 55, to col. 9, line 17. **Olbrich does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**.

Appellants submit that the combination of references does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose. **Importantly, Wolf describes the use of a fast response thermistor to measure air temperature and validate the proper inhalation sequence. Wolf does not teach or suggest using the fast response thermistor to detect whether the device is "properly positioned."**

Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

(2) The improvement suggested is not a predictable use of prior art elements according to their established functions

Further, the improvement suggested by the Examiner is not a predictable use of prior art elements according to their established functions as required in *KSR* **because Olbrich's sensor would destroy the established function of Wolf's monitoring device**. The combination of references provides no teaching or suggestion to replace Wolf's fast response thermistor with the body temperature sensor of Olbrich. In fact, Wolf offers other possible sensors that can be substituted for the thermistor including audio sensors or piezo sensors, as discussed above. Therefore, one of ordinary skill in the art would not have predictably used the Olbrich body temperature sensor in place of Wolf's fast response thermistor **because Olbrich's sensor would destroy the established function of Wolf's monitoring device. Olbrich's body temperature sensor would not meet the requirements of Wolf's rapid response thermistor to measure rapid changes in air temperature required to monitor and validate the proper inhalation sequence of Wolf's monitoring device.**

Olbrich teaches that "body temperature is measured by a temperature sensor ***mounted outside the airflow path***." (emphasis added) *See* Olbrich at col. 8, lines 64-67. Further, Olbrich notes that "a temperature sensor can be mounted to the mouthpiece at the proximal end of the device for measuring the temperature of the user's lips." *See* Olbrich at col. 8, line 67 through col. 9, line 2. The temperature sensor

of Olbrich is certainly outside the airflow path and is placed in contact with the user's mouth. Placing the temperature sensor of Olbrich on the device of Wolf would be to place a body temperature sensor outside of the airflow path in contact with the user's mouth. By doing so, the device of Wolf would be unsatisfactory for the intended purpose of measuring rapid changes in air temperature required to monitor and validate the proper inhalation sequence of Wolf's monitoring device. Therefore, Olbrich's sensor would destroy the established function of Wolf's monitoring device.

Accordingly, whether taken alone, or in combination, the cited references do not indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR,* because replacing the rapid response thermistor of Wolf with the body temperature sensor of Olbrich would destroy the established function of Wolf's monitoring device.

(3) No reasonable expectation of success

Further, the combination of references does not provide a reasonable expectation that the proposed modification would have been successful at the time of filing. One of ordinary skill in the art reading the references would not have had a reasonable expectation of successfully using the Olbrich body temperature sensor in place of Wolf's fast response thermistor because Olbrich's sensor measures body temperature, rather than air temperature, and is placed outside the airflow path of the device. As stated above, Wolf's thermistor is measuring the air temperature change to measure the direction of airflow. One would not reasonably expect the body temperature sensor of Olbrich, which is placed outside the airflow path, to measure the

air temperature change and thereby determine the direction of airflow to validate the proper inhalation sequence.

Accordingly, whether taken alone, or in combination, the cited references do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing, as required by *KSR*.

Accordingly, for each of these reasons outlined above, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 1-5, 7, 8, 12-22 and 25 and remand the case back to the Examiner to issue a Notice of Allowance.

B. Rejection of claims 6 and 9 under 35 U.S.C. § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 U.S.C. § 103(a) as obvious over US Patent No. 5,809,997 to Wolf in view of US Patent No. 6,733,464 to Olbrich, as applied to claim 1 above, and further in view of US Patent No. 7,073,499 to Reinhold is improper and should be reversed.

Appellants respectfully submit that Wolf in combination with Olbrich and Reinhold does not render Appellants' pending claims obvious for at least the following reasons.

A brief outline of relevant authority is set forth above in Section A.

As discussed above in Section A, independent claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and

the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Amended claim 6 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is for topical administration of the drug.

Amended claim 9 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebuliser.

The combination of Wolf and Olbrich is discussed in detail above in section A. The full discussion of Wolf and Olbrich is incorporated herein by reference. Briefly, Wolf describes the use of a fast response thermistor to measure air temperature and validate the proper inhalation sequence. Wolf does not teach or suggest using the fast response thermistor to detect body temperature or whether the device is "properly positioned." Further, Olbrich describes the use of a temperature sensor for recording body temperature but does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose. Olbrich does not remedy the deficiencies of Wolf because Olbrich's body temperature sensor would not meet the requirements of Wolf's rapid response thermistor to measure rapid **changes in air temperature required to monitor and validate the proper inhalation sequence** of Wolf's monitoring device. In fact, replacing the rapid response thermistor of Wolf with the body temperature sensor of Olbrich,

which is placed outside the airflow path, would destroy the established function of measuring changes in air temperature of Wolf's monitoring device.

Reinhold does not remedy the deficiencies of the combination of Wolf and Olbrich. Reinhold generally describes that a respiratory delivery system, for example, an inhaler, could be used for topical or nasal delivery of gaseous substances. *See* Reinhold at col. 14, lines 58-63. Further, Reinhold describes that respiratory delivery systems can be metered dose inhalers, dry powder inhalers or nebulisers. *See* Reinhold at col. 1, lines 25-28. However, like Wolf and Olbrich, Reinhold fails to teach or suggest a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth, as recited in claim 1. Additionally, Appellants submit that Reinhold do not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed.

Accordingly, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, none of Wolf, Olbrich, and Reinhold teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In addition, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Reinhold do not indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*.

Further, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Reinhold do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

Accordingly, for each of these reasons outlined above, Appellants respectfully request the Board of Patent Appeals and Interferences reverse the present rejection of pending claims 6 and 9 and remand the case back to the Examiner to issue a Notice of Allowance.

C. Rejection of claim 11 under 35 U.S.C. § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 U.S.C. § 103(a) as obvious over US Patent No. 5,809,997 to Wolf in view of US Patent No. 6,733,464 to Olbrich, as applied to claim 1 above, and further in view of US Patent No. 6,684,880 to Trueba is improper and should be reversed.

A brief outline of relevant authority is set forth above.

As discussed, independent claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting

whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Claim 11 is directed to the compliance monitor according claim 1, further comprising a light sensor for sensing when the sensor is covered.

The combination of Wolf and Olbrich is discussed in detail above in sections A and B. The full discussion of Wolf and Olbrich is incorporated herein by reference. Briefly, Wolf describes the use of a fast response thermistor to measure air temperature and validate the proper inhalation sequence. Wolf does not teach or suggest using the fast response thermistor to detect body temperature or whether the device is "properly positioned." Further, Olbrich describes the use of a temperature sensor for recording body temperature but does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose. Olbrich does not remedy the deficiencies of Wolf because Olbrich's body temperature sensor, which is placed outside the airflow path, would not meet the requirements of Wolf's rapid response thermistor to measure rapid **changes in air temperature required to monitor and validate the proper inhalation sequence** of Wolf's monitoring device. In fact, replacing the rapid response thermistor of Wolf with the body temperature sensor of Olbrich would destroy the established function of Wolf's monitoring device.

Trueba does not remedy the deficiencies of the combination of Wolf and Olbrich. Trueba merely describes the use of an optical sensor. *See* Trueba at col. 13, lines 28-31. However, like Wolf and Olbrich, Trueba fails to teach or suggest a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth, as recited in claim 1. Additionally, Appellants submit that Trueba does not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed.

Accordingly, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, none of Wolf, Olbrich, and Trueba teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In addition, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Trueba do not indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*.

Further, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Trueba do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

Accordingly, Appellants respectfully request the Board of Patent Appeals and Interferences reverse the present rejection of pending claim 11 and remand the case to the Examiner to issue a Notice of Allowance.

In view of the foregoing, Appellants respectfully request the reversal of the Examiner's rejections and the allowance of the pending claims. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 14-0112.

Respectfully submitted,

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9. Claims Appendix

1. (Previously presented) A compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising:

a switch actuatable by a user on delivering a dose from the device;

a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and

a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

2. (Previously presented) The compliance monitor according to claim 1, which does not affect the normal operation of the drug delivery device.

3. (Previously presented) The compliance monitor according to claim 1, which is removably attachable to the drug delivery device.

4. (Previously presented) The compliance monitor according to claim 1, comprising a clock coupled to the processor and in which the time of actuation of the switch is recorded.

5. (Previously presented) The compliance monitor according to claim 1, wherein the proper positioning of the drug delivery device is positioning in contact with or relative to the user's mouth, nose or skin.

6. (Previously presented) The compliance monitor according to claim 1, wherein the drug delivery device is for topical administration of the drug.

7. (Previously presented) The compliance monitor according to claim 1, wherein the drug delivery device is for oral administration of the drug.

8. (Previously presented) The compliance monitor according to claim 1, wherein the drug delivery device is an inhaler operated by the user depressing a pressurized canister containing the drug, and wherein the switch is a pressure-operated switch actuatable as the user depresses the canister.

9. (Previously presented) The compliance monitor according to claim 1, wherein the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebuliser.

10. (Canceled)

11. (Previously presented) The compliance monitor according claim 1, further comprising a light sensor for sensing when the sensor is covered.

12. (Previously presented) The compliance monitor according to claim 1, further comprising a conductivity sensor for sensing body conductivity.

13. (Previously presented) The compliance monitor according to claim 1, in which a change in an output of the sensor characteristic of correct use of the drug delivery device is used to determine whether the device was properly positioned when the dose was delivered.

14. (Previously presented) The compliance monitor according to claim 1, further comprising an output for downloading data to a docking station or a computer.

15. (Previously presented) The compliance monitor according to claim 1, in which the data comprises a compliance record of use of the drug delivery device, including a record of whether the sensor output indicates that the device was properly positioned on each occasion that a dose has been delivered.

16. (Previously presented) A docking station for use with a compliance monitor as defined in claim 1.

17. (Previously presented) A computer-readable medium carrying a computer program for programming a general purpose computer to receive and process data downloaded from a compliance monitor as defined in claim 1.

18. (Previously presented) A drug delivery device comprising a compliance monitor as defined in claim 1.

19. (Previously presented) A method of using a compliance monitor as defined in claim 1, to monitor use of a drug delivery device for administration of a drug, comprising the steps of:

determining when a user operates the device to deliver a dose of the drug;

sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered; and

recording for each operation of the device whether or not the device was properly positioned.

20. (Previously presented) The method according to claim 19, further comprising the step of determining and recording the time of each operation of the device.

21. (Previously presented) The method according to claim 19, in which the drug delivery device is for oral administration of the drug and proper positioning of the device is proper positioning in the user's mouth.

22. (Previously presented) The method according to claim 19, further comprising the step of downloading recorded data from the compliance monitor to a docking station or a computer to allow a compliance record to be reviewed.

23. - 24. (Canceled)

25. (Previously presented) The compliance monitor according to claim 7, wherein the drug delivery device is for oral administration by inhalation.

10. Evidence Appendix

1. Davis et al. "Body Temperature," WebMD article, http://firstaid.webmd.com/body-temperature, last updated February 20, 2009.

2. Vorvick et al., "Temperature Measurement," U.S. National Library of Medicine, National Institutes of Health, http://www.nlm.nih.gov/medlineplus/ency/article/003400.htm, last updated May 13, 2010

11. Related Proceedings Appendix

No information is appended under this section.

Article Link: http://firstaid.webmd.com/body-temperature

firstaid&emergencies

Please call 911 immediately if you are having chest pain, difficulty breathing, severe bleeding, sudden weakness or numbness, or if you think you have a medical emergency.

Body Temperature

What is body temperature?

Body temperature is a measure of the body's ability to generate and get rid of heat. The body is very good at keeping its temperature within a narrow, safe range in spite of large variations in temperatures outside the body.

When you are too hot, the blood vessels in your skin expand (dilate) to carry the excess heat to your skin's surface. You may begin to sweat, and as the sweat evaporates, it helps cool your body. When you are too cold, your blood vessels narrow (contract) so that blood flow to your skin is reduced to conserve body heat. You may start shivering, which is an involuntary, rapid contraction of the muscles. This extra muscle activity helps generate more heat. Under normal conditions, this keeps your body temperature within a narrow, safe range.

Where is body temperature measured?

Your body temperature can be measured in many locations on your body. The mouth, ear, armpit, and rectum are the most commonly used places. Temperature can also be measured on your forehead.

What are Fahrenheit and Celsius?

Thermometers are calibrated in either degrees Fahrenheit (°F) or degrees Celsius (°C), depending on the custom of the region. Temperatures in the United States are often measured in degrees Fahrenheit, but the standard in most other countries is degrees Celsius.

What is normal body temperature?

Most people think of a "normal" body temperature as an oral temperature of 98.6F. This is an average of normal body temperatures. Your temperature may actually be 1°F (0.6°C) or more above or below 98.6F. Also, your normal body temperature changes by as much as 1°F (0.6°C) throughout the day, depending on how active you are and the time of day. Body temperature is very sensitive to hormone levels and may be higher or lower when a woman is ovulating or having her menstrual period.

A rectal or ear (tympanic membrane) temperature reading is 0.5 to 1°F (0.3 to 0.6°C) higher than an oral temperature reading. A temperature taken in the armpit is 0.5 to 1°F (0.3 to 0.6°C) lower than an oral temperature reading.

What is a fever?

In most adults, an oral temperature above 100F or a rectal or ear temperature above 101F is considered a fever. A child has a fever when his or her rectal temperature is 100.4F or higher.

What can cause a fever?

A fever may occur as a reaction to:

- Infection. This is the most common cause of a fever. Infections may affect the whole body or a specific body part (localized infection).
- Medicines, such as antibiotics, narcotics, barbiturates, antihistamines, and many others. These are called drug fevers. Some medicines, such as antibiotics, raise the body temperature directly; others interfere with the body's ability to readjust its temperature when other factors cause the temperature to rise.
- Severe trauma or injury, such as a heart attack, stroke, heat exhaustion or heatstroke, or burns.
- Other medical conditions, such as arthritis, hyperthyroidism, and even some cancers, such as leukemia, Hodgkin's lymphoma, and liver and lung cancer.

Can a low body temperature be dangerous?

An abnormally low body temperature (hypothermia) can be serious, even life-threatening. Low body temperature may occur from cold exposure, shock, alcohol or drug use, or certain metabolic disorders, such as diabetes or hypothyroidism. A low body temperature may also be present with an infection, particularly in newborns, older adults, or people who are frail. An overwhelming infection, such as sepsis, may also cause an abnormally low body temperature.

Can a high body temperature be dangerous?

Heatstroke occurs when the body fails to regulate its own temperature, and body temperature continues to rise. Symptoms of heatstroke include mental changes (such as confusion, delirium, or unconsciousness) and skin that is red, hot, and dry, even under the armpits.

Classic heatstroke can develop without exertion when a person is exposed to a hot environment and the body is unable to cool itself effectively. In this type of heatstroke, the body's ability to sweat and transfer the heat to the environment is reduced. A person with heatstroke may stop sweating. Classic heatstroke may develop over several days. Babies, older adults, and people with chronic health problems have the greatest risk of this type of heatstroke.

Exertional heatstroke may develop when a person is working or exercising in a hot environment. A person with heatstroke from exertion may sweat profusely, but the body still produces more heat than it can lose. This causes the body's temperature to rise to high levels.

Both types of heatstroke cause severe dehydration and can cause body organs to stop functioning. **Heatstroke is a life-threatening medical emergency**, requiring emergency medical treatment.

Why It Is Done

Body temperature is checked to:

- Detect fever.
- Detect abnormally low body temperature (hypothermia) in people who have been exposed to cold.
- Detect abnormally high body temperature (hyperthermia) in people who have been exposed to heat.
- Help monitor the effectiveness of a fever-reducing medicine.
- Help plan for pregnancy by determining if a woman is ovulating.

How To Prepare

Take your temperature several times when you are feeling well to find out what is normal for you. Check your temperature in both the morning and evening, since body temperature can vary by as much as 1°F (0.6°C) throughout the day.

Wait at least 20 to 30 minutes after smoking, eating, or drinking a hot or cold liquid before taking your temperature. Also wait at least an hour after vigorous exercise or a hot bath.

Several different types of thermometers are available:

Electronic thermometers are plastic and shaped like a pencil, with a display window at one end and the temperature probe at the other end. They work by measuring how well electricity travels through a wire. Electronic thermometers are used in the mouth, rectum, or armpit. They are easy to use, easy to read, and are accurate. If you buy an electronic thermometer, check the package for information about its accuracy. See a picture of an electronic thermometer  .

Ear thermometers are plastic and come in different shapes. They use infrared energy to measure body temperature. The small cone-shaped end of the thermometer is placed in the ear, and body temperature shown on a digital display. The results appear within seconds. Some models also show the corresponding oral and rectal readings. See a picture of an ear thermometer  .

Forehead thermometers use skin temperature to determine body temperature. Some have a soft disc that are pressed against the forehead and show the temperature on a digital display. Other types are thin pieces of plastic with numbers on them. You press the strip against a person's forehead, and the temperature makes some numbers change colors or light up. These thermometers are not as accurate as electronic and ear thermometers.

Disposable thermometers are thin flat pieces of plastic with colored dots and temperature markings on one end. The color of the dots shows the temperature. Disposable thermometers can be used in the mouth or rectum. A patch form can be used on a baby's skin to measure temperature continuously for 48 hours. These thermometers are safe and accurate within 0.2°F (0.1°C). They do not contain glass, latex, or mercury. You can reuse the thermometer during an illness and then throw it away.

Pacifier thermometers are shaped like a baby's pacifier but have a display that shows the temperature. You place the pacifier in your child's mouth to measure temperature. These thermometers may take longer to get a reading and are not as accurate as other types.

Glass thermometers containing mercury are no longer recommended. If you have a glass thermometer, contact your local health department for instructions on how to dispose of it safely. If you break a glass thermometer, call your local poison control center immediately.

How It Is Done

Before taking a body temperature, review the instructions for how to use your thermometer. Methods of taking a temperature are described below.

How to take an oral temperature

Oral is the most common method of taking a temperature. To get an accurate temperature, the person must be able to breathe through the nose. If this is impossible because of a stuffy nose or lack of cooperation, use the rectum or armpit to take the temperature.

1. Place the digital or disposable thermometer under the tongue, just to one side of the center, and close the lips tightly around it.
2. Leave the thermometer in place for the required amount of time. Time yourself with a clock or watch. Some digital thermometers give a series of short beeps when the reading is done.
3. Remove the thermometer and read it.
4. Clean a digital thermometer with cool, soapy water and rinse it off before putting it away.

How to take a rectal temperature

This is the location to measure body temperature most accurately. It is recommended for babies, small children, and people who cannot hold a thermometer safely in their mouths. It is also used when getting the most accurate measurement is essential.

1. Apply a lubricant jelly or petroleum jelly, such as Vaseline, on the bulb of the thermometer so that you can insert it easily.
2. When measuring the temperature of babies or small children, turn the child face down on your lap or on a flat covered or padded surface, such as a bed. Choose a quiet place so that the child won't be distracted or move around too much.
3. Spread the child's buttocks with one hand and gently insert the bulb end of the rectal thermometer about 0.5in to 1in into the anal canal with your other hand. Don't force it into the rectum. Hold the thermometer in place with two fingers close to the anal opening (not near the end of the thermometer). Pressing the child's buttocks together will help keep the thermometer in place.
4. Leave the thermometer in place for the required amount of time. Some digital thermometers give a series of short beeps when the reading is done. Time yourself with a watch or clock.
5. Remove the thermometer and read it. A rectal temperature reading may be as much as 1°F (0.6°C) higher than an oral temperature reading.
6. Clean a digital thermometer with cool, soapy water and rinse it off before putting it away.
7. Do not use a thermometer to take an oral temperature after it has been used to take a rectal temperature.

See a picture of how to take the rectal temperature of a baby.

How to take an armpit (axillary) temperature

Taking a temperature in the armpit may not be as accurate as taking an oral or rectal temperature.

1. Place the thermometer under the arm with the bulb in the center of the armpit.
2. Press the arm against the body and leave the thermometer in place for the required amount of time. Time yourself with a watch or clock.
3. Remove the thermometer and read it. An armpit temperature reading may be as much as 1°F (0.6°C) lower than an oral temperature reading.
4. Clean a digital thermometer with cool, soapy water and rinse it off before putting it away.

How to take an ear temperature

Ear thermometers may need to be cleaned and prepared for use. These steps can be followed when using an ear thermometer; however, follow the instructions for your specific model.

1. Check that the probe is clean and free of debris. If dirty, wipe it gently with a clean cloth. Do not immerse the thermometer in water.
2. To keep the probe clean, a disposable probe cover should be used. Use a new probe cover each time you take an ear temperature. Attach the disposable cover to the probe.
3. Turn the thermometer on.
4. For babies younger than 12 months, pull the earlobe down and back. This will help place the probe in the ear canal. Center the probe tip in the ear and push gently inward toward the eardrum.

5. For children older than 12 months and for adults, pull the earlobe up and back. Center the probe tip in the ear and push gently inward toward the eardrum.
6. Press the "on" button to display the temperature reading.
7. Remove the thermometer and throw away the used probe cover.

How to take a forehead temperature

1. Press the soft cup of the thermometer or the entire plastic strip firmly against a dry forehead.
2. Hold the thermometer in place for the required amount of time. Time yourself with a watch or clock.
3. Read the temperature before removing the thermometer.
4. Clean the thermometer with cool soapy water and rinse it off before putting it away.
5. Forehead thermometers are not as accurate as electronic and ear thermometers. If your baby is younger than 3 months or your child's fever rises higher than 102F, recheck the temperature using a better method.

How to use a pacifier thermometer

1. Put together all of the pieces of the pacifier if you need to. Some pacifier thermometers can be used as regular pacifiers and need to have the temperature part attached.
2. Let your child suck on the nipple for the required amount of time. Time yourself with a watch or clock.
3. Remove the pacifier and read the temperature.
4. Clean the pacifier with cool, soapy water and rinse it off before putting it away.
5. Pacifier thermometers are not as accurate as electronic and ear thermometers. If your baby is younger than 3 months or your child's fever rises higher than 102F, recheck the temperature using a better method.

How It Feels

Taking your temperature by mouth is only mildly uncomfortable, since you must keep your mouth closed and breathe through your nose while the thermometer is in place.

Taking a rectal temperature can be slightly uncomfortable but should not be painful.

Taking your temperature with an ear thermometer causes little or no discomfort. It is not inserted very far into the ear, and it provides a reading in only a few seconds. For this reason, the ear thermometer is widely used in health professional's offices and hospitals. But it may be less accurate than rectal thermometers.

Taking your temperature with a plastic strip thermometer feels like having an adhesive bandage on your forehead. Although it causes very little discomfort, it is not as reliable as other methods, so another kind of thermometer should be used if the plastic strip shows an abnormal temperature.

Risks

There is very little risk of complications from taking a temperature.

When taking a rectal temperature, do not insert the thermometer into the rectum more than 0.5in to 1in. Further insertion can be painful and may damage rectal tissues.

Results

Body temperature is a measure of the body's ability to generate and get rid of heat.

Rectal and ear (tympanic membrane) temperatures are normally as much as 1°F (0.6°C) higher than oral temperatures; armpit temperatures, however, may be as much as 1°F (0.6°C) lower than oral temperatures. Forehead temperatures also are usually lower than oral or rectal temperatures. If your oral temperature is 99F, your rectal or ear temperature may be about 100F and your armpit temperature about 98F. When you tell your health professional about your temperature measurement, be sure to mention whether it was taken on the forehead or in the mouth, rectum, armpit, or ear.

Body temperature

Normal:	The average normal temperature is 98.6F. But "normal" varies from person to person. Your temperature will also vary throughout the day, usually being lowest in the early morning and rising as much as 1°F (0.6°C) in the early evening. Your temperature may also rise by 1°F (0.6°C) or more if you exercise on a hot day. A woman's body temperature typically varies by 1°F (0.6°C) or more through her menstrual cycle, peaking around the time of ovulation.

Abnormal:	An oral temperature of 100F or a rectal, ear, or forehead temperature of 101F indicates a slight fever.
	A rectal temperature of 100.4F or higher in a child indicates a fever.
	A rectal or ear temperature of less than 97F indicates a low body temperature (hypothermia).

What Affects the Test

Inaccurate temperature readings can be caused by:

Not keeping your mouth closed around the thermometer when taking an oral temperature.

Not leaving a thermometer in place long enough before reading it.

Not putting the proper thermometer in the right place.

Not following the instructions for proper use that come with the thermometer.

A weak or dead thermometer battery.

Taking an oral temperature within 20 minutes after smoking or drinking a hot or cold liquid.

Taking a temperature by any method within an hour of exercising vigorously or taking a hot bath.

What To Think About

Thermometers with a digital display usually need a battery. If your thermometer uses a battery, make sure it is working before taking a temperature.

Body temperature is only one way of monitoring your health. Besides temperature, other basic measurements to monitor your health include your pulse, breathing rate (respiration), and blood pressure. These basic measurements are called your vital signs.

A fever can make you feel uncomfortable. To treat the discomfort of a fever, wear light clothing and use light blankets or other bedding. Drink cool liquids. A bath or shower with lukewarm (not cool) water can lower body temperature. Cool or cold water can cause shivering and can cause the blood vessels near the skin to contract, which will raise the body temperature further.

Fever-reducing medicines can lower body temperature. Unless a fever is high enough to call a health professional, fever-reducing medicine is not necessary but may help you feel more comfortable. When a fever causes discomfort, use acetaminophen (such as Tylenol) or ibuprofen (such as Advil or Motrin). Aspirin also reduces fever but should not be given to anyone younger than age 20 because of the risk of Reye syndrome.

When reading medical information that mentions body temperatures, note whether the temperature is listed as an oral or rectal temperature. Many books and other information about children's health list all body temperatures as rectal temperatures, because this method is preferred for measuring body temperature in a young child. If a body temperature is listed but neither oral nor rectal is specified, you may assume it is an oral temperature.

Glass thermometers containing mercury are no longer recommended. If you have a glass thermometer, contact your local health department for instructions on how to dispose of it safely. If you break a glass thermometer, call your local poison control center immediately.

Other Works Consulted

Auwaerter PG (2007). Approach to the patient with fever. In LR Barker et al., eds., Principles of Ambulatory Medicine, 7th ed., pp. 457-465. Philadelphia: Lippincott Williams and Wilkins.

El-Radhi AS, Barry W (2006). Thermometry in paediatric practice. Archives of Disease in Childhood, 91(4): 351-356.

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Temperature measurement

URL of this page: http://www.nlm.nih.gov/medlineplus/ency/article/003400.htm

Temperature measurement is a method to take a person's temperature and determine whether it is within a normal range. A high temperature is a fever.

How the Test is Performed

In the past, a glass thermometer filled with mercury was used to measure body temperature. However, the American Academy of Pediatrics (AAP) recommends against using mercury thermometers because the glass can break, and mercury is poisonous.

Electronic thermometers are most commonly used and recommended. The temperature is displayed on a digital readout. Follow the directions that come with the thermometer. Electronic probe thermometers can be placed in the mouth, rectum, or armpit.

Plastic strip thermometers change color to indicate the temperature. This method is the least accurate. Place the strip on the forehead and read it after 1 minute. Read it while the strip is in place. Plastic strip thermometers for the mouth are also available.

Always clean the thermometer before using. You can use cool, soapy water or rubbing alcohol. If you are using a glass thermometer, grip the end opposite the bulb and shake the thermometer downwards until it reads 95°F or less.

You can measure the temperature on three body locations:

- Mouth -- place the thermometer under the tongue and close the mouth. Breathe through the nose, and use the lips to hold the thermometer tightly in place. Leave the thermometer in the mouth for 3 minutes or until the device beeps.
- Rectum -- this method is for infants and small children who are not able to hold a thermometer safely in their mouths. Place petroleum jelly on the bulb of a rectal thermometer. Place the small child face down on a flat surface or lap. Spread the buttocks and insert the bulb end of the thermometer about 1/2 to 1 inch into the anal canal. Be careful not to insert the thermometer too far. Prevent the child from struggling, since this can accidentally push the thermometer in further. Remove the thermometer after 3 minutes or when the device beeps.
- Armpit -- place the thermometer in the armpit, with the arm pressed against the body for 5 minutes before reading. This is the least accurate method for using a glass thermometer.

Electronic ear thermometers are common and convenient, but some users report that the results are less consistent than probe thermometers.

Digital thermometers have easy-to-read displays. To read a glass thermometer, gripping the end opposite the bulb so that the numbers are facing you. Roll the thermometer back and forth between your fingers until you see a silver or red reflection in the column. Compare the end of the column with the

degree marking in the lines on the thermometer.

How to Prepare for the Test

Wait at least 1 hour after vigorous exercise or a hot bath before measuring body temperature. Wait for 20 to 30 minutes after smoking, eating, or drinking a hot or cold liquid.

How the Test Will Feel

There is very little discomfort.

Why the Test is Performed

The measurement of body temperature determines whether a person has a fever. It may be helpful in monitoring to see if a person is ill or whether a treatment is working -- especially in antibiotic treatment of infections.

Normal Results

The normal temperature varies by person, age, time of day, and where on the body the temperature was taken. The average normal body temperature is 98.6°F (37°C).

Your body temperature is usually highest in the evening. It can be raised by physical activity, strong emotion, eating, heavy clothing, medications, high room temperature, and high humidity.

Daily variations change as children get older:

- In children younger than 6 months of age, the daily variation is small.
- In children 6 months to 2 years old, the daily variation is about 1 degree.
- By age 6, daily variations gradually increase to 2 degrees per day.
- Body temperature varies less in adults. However, a woman's menstrual cycle can raise temperature by one degree or more.

For information on when to call a doctor due to specific temperatures and ages, see the article on fever.

What Abnormal Results Mean

If the reading on the thermometer is more than 1 to 1.5 degrees above the patient's normal temperature, the patient has a fever. Most fevers are a sign of infection and occur with other symptoms. Abnormally high or low temperatures can be serious, and you should consult a health care provider.

Risks

There is essentially no risk. There is a rare risk of bowel perforation if the rectal thermometer is not carefully inserted.

References

Mackowiak PA. Temperature regulation and pathogenesis of fever. In: Mandell GL, Bennett JE, Dolin R, eds. *Principles and Practice of Infectious Diseases*. 7th ed. Philadelphia, Pa: Elsevier Churchill Livingstone; 2009:chap 50.

Powell KR. Fever. In: Kliegman RM, Behrman RE, Jenson HB, Stanton BF, eds. *Nelson Textbook of Pediatrics*. 18th ed. Philadelphia, Pa: Saunders Elsevier; 2007:chap 174.

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